

**§ 147.52**

**9 CFR Ch. I (1–14 Edition)**

(NPIP staff) every 3 years. The Service's review may include, but will not necessarily be limited to, checking records, laboratory protocol, check-test proficiency, technician training, and peer review.

(f) *Reporting.* (1) A memorandum of understanding or other means shall be used to establish testing and reporting criteria to the Official State Agency, including criteria that provide for reporting H5 and H7 low pathogenic avian influenza directly to the Service.

(2) *Salmonella pullorum* and *Mycoplasma* Plan disease reactors must be reported to the Official State Agency within 48 hours.

(g) *Verification.* Random samples may also be required to be submitted for verification as specified by the Official State Agency.

**§ 147.52 Approved tests.**

(a) The procedures for the bacteriological examination of poultry and poultry environments described in this part are approved tests for use in the NPIP. In addition, all tests that use veterinary biologics (e.g., antiserum and other products of biological origin) that are licensed or produced by the Service and used as described in this part are approved for use in the NPIP.

(b) Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) may be approved through the following procedure:

(1) The sensitivity of the kit will be estimated in at least three authorized laboratories selected by the Service by testing known positive samples, as determined by the official NPIP procedures found in Subparts A, B, C, and D of this part. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(2) The specificity of the kit will be estimated in at least three authorized laboratories selected by the Service by testing known negative samples, as determined by the official NPIP procedures found in this part. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and sig-

nificance of the effect(s) can be evaluated.

(3) The kit will be provided to the cooperating laboratories in its final form and include the instructions for use. The cooperating laboratories must perform the assay exactly as stated in the supplied instructions. Each laboratory must test a panel of at least 25 known positive clinical samples supplied by the manufacturer of the test kit. In addition, each laboratory will be asked to test 50 known negative clinical samples obtained from several sources, to provide a representative sampling of the general population. The identity of the samples must be coded so that the cooperating laboratories are blinded to identity and classification. Each sample must be provided in duplicate or triplicate, so that error and repeatability data may be generated.

(4) Cooperating laboratories will submit to the kit manufacturer all raw data regarding the assay response. Each sample tested will be reported as positive or negative, and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value.

(5) The findings of the cooperating laboratories will be evaluated by the NPIP technical committee, and the technical committee will make a recommendation regarding whether to approve the test kit to the General Conference Committee. If the technical committee recommends approval, the final approval will be granted in accordance with the procedures described in §§ 147.46 and 147.47.

(c) The following diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) are approved for use in the NPIP:

(1) Rapid Chek<sup>®</sup>; Select TMSalmonella Test Kit, Strategic Diagnostics, Inc., Newark, DE 19713.

(2) ADIAFOOD Rapid Pathogen Detection System for *Salmonella* spp., AES Chemunex Canada. Laval, QC (Canada) H7L4S3.

(3) DuPont Qualicon BAX Polymerase Chain Reaction (PCR)-based assay for *Salmonella*, DuPont Qualicon, Wilmington, DE 19810.

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